

Juices" is being issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Dockets Management Branch (*see ADDRESSES*) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/~dms/guidance.html>.

Dated: September 27, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02D-0384]

#### **Draft Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing" (the draft guidance). The draft guidance advises juice processors of FDA's view that the first edition of the "Juice HACCP Training Curriculum" of the Juice HACCP Alliance (the standardized curriculum) is adequate for use in

training individuals to meet the requirements of the juice hazard analysis and critical control point (HACCP) regulation. The draft guidance also advises processors and educators on how the requirements of the juice HACCP regulation may be met using the standardized curriculum or alternative curricula for training individuals and on how they can view, download, or purchase the standardized curriculum.

**DATES:** Submit written or electronic comments concerning this draft guidance by December 6, 2002, to ensure adequate consideration in preparation of the final guidance document. Comments on this draft guidance may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to Michael E. Kashtock, (*see FOR FURTHER INFORMATION CONTACT*). Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

#### **FOR FURTHER INFORMATION CONTACT:**

Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2022, FAX 301-436-2651, e-mail: [mkashtoc@cfsan.fda.gov](mailto:mkashtoc@cfsan.fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

### I. Background

FDA's juice HACCP regulation in part 120 (21 CFR part 120) includes in §120.13 a requirement that individuals who perform certain specified functions, e.g., developing the hazard analysis or the HACCP plan, "shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions." This draft guidance advises juice processors of FDA's view that the first edition of the "Juice HACCP Training Curriculum" of the Juice HACCP Alliance (coordinated through the efforts of the National Center for Food Safety and Technology at the Illinois Institute of Technology) (the standardized curriculum) is adequate

for use in training individuals to meet the requirements of the juice HACCP regulation. This guidance also advises processors and educators on how the requirements of the juice HACCP regulation may be met using the standardized curriculum or alternative curricula for training individuals and on how they can view, download, or purchase the standardized curriculum.

The draft guidance entitled "Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing," is being issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency's current thinking on curricula for training juice processing personnel in the application of HACCP principles to juice processing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## II. Comments

Interested persons may submit to the Dockets Management Branch (*see ADDRESSES*) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at the CFSAN Web site at <http://www.cfsan.fda.gov/~dms/guidance.html>.

Dated: September 27, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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